

REMARKS

It is noted that the Notice of Non-Compliant Amendment has been withdrawn, as have the objection to and rejection of claims 32-34 under 35 USC 12, and the rejection of claims 15-23 and 25-30, also under 35 USC 112.

The specification is objected to because the Abstract does not appear on a separate page. The objection is traversed. The Examiner's attention is directed to the enclosure to the Amendment dated April 29, 2008, which is a replacement page 10, i.e., the Abstract on a separate page. This Abstract has already been scanned by the Office and appears in the PAIR system. It is deemed that objection is moot.

The Examiner's comments regarding old claim 32, which recited a clearly erroneous amount of active are found to be confusing. The Examiner states that it is not persuasive that the claim contained an obvious typographical error because other claims (since amended to correct the error) also contained lesser amounts of active. However, as applicant has argued, amounts less than 0.1% were stated in the Amendment of April 29, 2008 to be inoperative (see page 8 thereof, "...0.1% is the minimum effective concentration..."). Said Amendment contained the claims with the obvious typographical errors. In view of applicant's admission that the claimed amount was inoperative, it is unclear why a search was done for compositions containing 0.01% active when, even if clear of the art, the claim would be rejected as inoperative. In view of this, it is again urged that the refusal to enter the Amendment of January 13, 2009 is deemed to be improper. The Amendment: 1) raised no new issues; 2) did not present additional claims without cancellation of a corresponding number of finally rejected claims; 3) did place the case in condition for allowance; and 4) did reduce the number of issues on appeal.

The Examiner makes reference (page 4 of the Action) to the "Amendment dated August 13, 2008". Applicant is not aware of such Amendment. Clarification is requested.

Regarding *In re Susi*, the Examiner objects to applicant's comments, stating that the purpose of citing *Susi* was to rebut applicant's arguments that *Asche* does not teach 0.1% sodium diclofenac. The Examiner states that *Asche* teaches 0.1-10% by weight of an NSAID *such as diclofenac sodium*. Stated this way, it appears that *Asche* teaches 0.1% diclofenac sodium. However, there is no such teaching in this reference. The Examiner refers to col 7, lines 45-54 in support of the rejection. However, the teaching there is that for the preferred actives, (e.g. diclofenac), the range is 1-5%, i.e. at least one order of magnitude greater than 0.1%. Although *Asche* does teach a range of 0.1-10%, this range applies only to the broad genus of NSAIDs, not specifically to diclofenac sodium. At col 7 and continuing to col 8, line 34 *Asche* teaches 22 active NSAID compounds and a very large number of possible salt forms thereof. This combination of

actives and salts amounts to well over 1000 compounds. This is not the basis for the statement that Asche teaches 0.1% diclofenac sodium, especially since the only references in Asche to this specific compound and an amount thereof is 1% diclofenac (at the bottom of col. 2) and even greater amounts in Examples 1-4. The Examiner also relies on the Asche Abstract. However, that also fails to teach 0.1% diclofenac sodium. It is requested that the Examiner explain how Susi can possibly rebut the argument. Further, if the Examiner persists in arguing that Asche makes such a teaching, then it is requested that she cite column/line where 0.1% diclofenac sodium is mentioned.

Claims 15-23 and 25-31 are rejected under 35 USC 103 as obvious solely over Asche (USP 4,917,886). The rejection is traversed. The Examiner points out the various components and ranges therefor taught by Asche but admits that nowhere does the reference teach any example where these components are within the presently claimed ranges. The Examiner concludes from this broad teaching that it would have obvious to one of ordinary skill to formulate the claimed compositions. Applicant disagrees. The Examiner's attention is directed to MPEP 2144.08, wherein the topic of a case of *prima facie* obviousness based on a reference is discussed at length. The MPEP points out that merely because the claimed subject matter is encompassed by the art is not sufficient to establish a case of *prima facie* obviousness. Rather, the Examiner must consider the factors set out in *Graham v. Deere*. The Examiner must find motivation or suggestion in the teaching to one of ordinary skill in the art to make the claimed invention.

The MPEP recites criteria which the Examiner should adhere to in making a case for *prima facie* obviousness. These include, but are not limited to: 1) identifying the motivation found in the art to make the invention; 2) evaluating the art from the standpoint of one of ordinary skill in the art; 3) determining whether one of ordinary skill would be motivated to make the invention (i.e., to actually select the claimed subject matter from the art's genus; 4) considering the preferred species taught in the art; 5) considering the number of variables which must be selected from the art to make the invention; and 6) specifically articulating what teaching or suggestions in the art would have motivated one of ordinary skill to select the claimed species or subgenera. Finally, MPEP 2144.08 states that conclusory statements without articulated rationale or evidentiary support do not constitute sufficient factual findings. Without these, it is deemed that there is no basis for the Examiner's rejection based on obviousness. It is requested that the Examiner comply with these criteria and specifically point out how they have been met. It is deemed that the Examiner has not met the burden of proof necessary for a rejection under 35 USC 103.

The Examiner's refusal to interpret certain claims narrowly ("consisting essentially of" is to be read as "comprising") absent an indication in the claims or specification what the basic and novel characteristics are is not understood. The Examiner's attention is directed to page 1, paragraphs 3,

4, and 5; page 2, paragraphs 1, 2, and 4 of the specification, from which it is clear what the basic and novel characteristics of the claimed compositions are. It is deemed that the refusal of the Examiner to examine the claims as they are presented and not as she has redrafted them is error. Re-examination of the claims as presented is requested.

Claims 32 and 35-36 are rejected under 35 USC 103 as obvious over Asche as applied above in view of Levine (USP 6,126,959) and Betlach II (USP 5,374,661). The rejection is traversed. Applicant's comments *re* Asche are repeated herein. The Examiner points out the various teachings of Asche and also the failure thereof regarding certain components of the claimed invention. The secondary references are cited to supplement Asche. Levine is deemed to be too remote and limited in its teaching to have been combined by one of ordinary skill in the art with Asche. The composition of Levine is intended for delivery of a β -adrenergic agonist to the vaginal mucosa. The advantageous property of this composition is said to be that it adheres to the mucosa and does not wash away easily (col. 7, ll 26-31). It is deemed that one of ordinary skill in the art would not have combined this teaching of a muco-adhesive composition with Asche. Furthermore, at col. 4, ll 49-53, Levine teaches that its bioadhesive carrier has been used in other systems *but with different results*. This is a teaching that the results one can expect to achieve are going to vary with the system. This, at best, is merely an invitation to experiment and not the kind of teaching that the person of ordinary skill in the art would use with an expectation of success; i.e., an invitation to experiment does not support an obviousness rejection. The Examiner next introduces Betlach II to supplement the teaching of Levine. This requires replacing some of the components of Levine and combining these with Asche. However, as argued above Levine's teaching is limited (has been used in different systems but with different results). Thus, the invitation to experiment now involves not only the components of Levine itself but the selective choices from Betlach II. This is an invitation further removed and even less supportive of an obviousness rejection.

It is requested that the Examiner reconsider the objections and rejections in view of the remarks and that the case be passed to issue.

Respectfully submitted,



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